

EXHIBIT 1

From: [Marlene Goldenberg](#)
To: ["DECValsartan@btlaw.com"](mailto:DECValsartan@btlaw.com)
Cc: [Valsartan PEC Listserv](#)
Subject: [EXTERNAL]Losartan and Irbesartan Core Discovery
Date: Tuesday, June 21, 2022 12:54:45 PM
Attachments: [Outlook-cdbwyr3x.png](#)
[2022.06.21 Core Discovery For Losartan and Irbesartan.docx](#)

Counsel,

We are reaching out to discuss core discovery for losartan and irbesartan. We are attaching our proposed categories which are nearly identical to the core discovery for valsartan. Please let us know if you will agree to these categories or if you would like to set up a time to meet and confer on this.

Thank you,

Marlene



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The responding defendants shall produce the following core discovery:

1. For API Manufacturer and Supplier Defendants
 - a. Losartan and Irbesartan ANDA file(s)
 - b. Losartan and Irbesartan Drug Master File(s)
 - c. Communications with the FDA relating to or concerning: (1) the ARB recalls, (2) the investigation into the cause of the alleged contamination, (3) efforts to contain, remove or detect the contamination, (4) supplements to the Losartan and Irbesartan Drug Master File re: manufacturing process changes from 2011 to present, (5) all FDA Form 483's¹, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue, and (6) a list of all United States customers from 2011 to present.
 - d. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.
 - e. All nitrosamine test results.
2. For Finished Product/Dose Manufacturer Defendants
 - a. ANDA file for each involved finished dosage formulation
 - b. Communications with the FDA described in paragraph 1.c. the extent not produced by another responding defendant, the discovery listed in paragraph 1.
 - c. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.
 - d. All nitrosamine test results.
3. For U.S. Agents for FDA Communications Defendants
 - a. To the extent not produced by another responding defendant, the discovery listed in paragraphs 1. and 2. Above
 - b. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

¹ Including any reply to FDA Form 483, related subsequent correspondence; the FDA inspection reports and exhibits; responses to that report and exhibits; and any related FDA correspondence and meeting minutes.